

**REMARKS**

**I. November 3, 2006, Interview**

In accordance with 37 C.F.R. § 1.133, Applicant submits this complete written statement of reasons warranting favorable action presented during a telephonic interview on November 3, 2006. Examiner Leon Lankford participated on behalf of the Office. Jessica Roark, Reg. No. 54,869, took part on behalf of Applicant.

In the interview, the participants discussed the Office Action mailed August 9, 2006, in which the Office maintained the rejection of record under 35 U.S.C. § 103(a), but indicated that “[c]laims commensurate in scope with [Applicant’s May 19, 2006 arguments] (using language fully supported by the specification) would appear to be free of the art, i.e., incorporating the limitations into claim 1 would appear to make claim 1 allowable.” (Office Action, pages 2-3.)

During the interview, Applicant’s representative inquired whether the incorporation of language indicating that the passage number of the production cells was between that of the master cell bank (MCB) and extended cell bank (ECB) would be sufficient to address Examiner Lankford’s concerns. After considering the disclosure on pages 3 and 4 regarding the definition of ECB, Examiner Lankford indicated that including language in independent claims 1 and 27 that indicated the production cells have a passage number between MCB and ECB should be sufficient, assuming Applicant could point to sufficient support in the specification regarding the term “ECB.”

In the accompanying amendment, Applicant has, as discussed, amended the independent claims to recite “wherein the passage number of each production batch is between master cell bank and extended cell bank.” Applicant appreciates Examiner’s

Lankford's indication that if, upon review of the amended claims, he finds that additional clarifying language is needed, he will contact the undersigned before issuing an Office Action.

## **II. Amendments and Status of the Claims**

Claims 1, 2, 7, 8, 11-18, 23-25, and 27 were pending. Claims 1 and 27 are independent.

Claims 1 and 27 have been amended without prejudice to the pursuit of any canceled subject matter in a continuing application, and without disclaimer of any subject matter. Support for the amendments to claims 1 and 27 can be found throughout the specification and original claims. In particular, claims 1 and 27 have been amended to recite "wherein the passage number of each production batch is between master cell bank and extended cell bank." The specification discloses on page 4, lines 27-31 that "[o]nce such ECB is fully characterized one may allow to produce the product with cells at any passage number between MCB and ECB." The term "ECB" is defined on page 3, footnote 2, and the specification describes the ECB as "a specific and characterised passage number [of production cells] . . . ." (Specification, page 3, lines 34-35.) The specification goes on to note that the ECB is validated "with respect to growth characteristics, freedom of adventitious, extraneous and endogenous agents at the different stages, karyology isoenzyme analysis and so on." (Specification, page 4, lines 26-29.) Accordingly, "[i]n the method according to the present invention the maximum number of cell passages can be defined by ECB." (Specification, page 4,

lines 19-20.) The term "MCB" is commonly understood by one of skill in the art and requires no additional definition.

Applicant has also added dependent claims 28-38 . These claims parallel claims 2, 7, 8, and 11-18, but depend from claim 27 rather than from claim 1. Support for claim 28 can be found at least in original claim 2. Support for claims 29 and 30 can be found at least in original claim 3. Support for claim 31 can be found at least in original claim 5. The specification at page 3, lines 9-10 and page 5, lines 15-31, among other locations, provides support for claims 32-38.

These amendments add no new matter. Claims 1, 2, 7, 8, 11-18, 23-25, and 27-38 are pending and under consideration.

### **III. Claim Rejection under 35 U.S.C. § 103**

Claims 1, 2, 7, 8, 11-18, 23-25, and 27 stand rejected as allegedly unpatentable over BRYAN GRIFFITHS & DENIS LOOBY, *Scale-Up of Suspension and Anchorage-Dependent Animal Cells*, in 75 METHODS IN MOLECULAR BIOLOGY: BASIC CELL CULTURE PROTOCOLS 59 (Jeffrey W. Pollard & John M. Walker eds., 2d ed. 1997) ("*Griffiths*") and JEFFREY W. POLLARD, *Basic Cell Culture*, in 75 METHODS IN MOLECULAR BIOLOGY: BASIC CELL CULTURE PROTOCOLS 1 (Jeffrey W. Pollard & John M. Walker eds., 2d ed. 1997) ("*Pollard* "). Office Action, page 3.

Applicant respectfully traverses this rejection for the reasons of record. Solely in order to expedite prosecution, however, claims 1 and 27 have been amended to explicitly recite "wherein the passage number of each production batch is between master cell bank and extended cell bank," as discussed in the November 3, 2006,

Interview. Applicant believes that this language is sufficient to address the Office's concerns and thereby obviates the rejection of record. Accordingly, Applicant respectfully requests that the rejection be withdrawn and the pending claims be allowed. Should the Office have any additional concerns, Applicant requests that the Office contact the undersigned before issuing an Office Action.

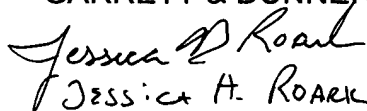
**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

  
Jessica A. Roark

Dated: November 9, 2006

By: Reg No. 54,869 For:  
Anthony C. Tridico  
Reg. No. 45,958